

JUL 11 2014

K141486
Page 1 of 4

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

Esaote Europe B.V.
Philipsweg 1
6227 AJ Maastricht
The Netherlands

Contact Person: Allison Scott, RAC
317.228.8719 Office
317.372.0276 Mobile
allison.scott@navigant.com

Date: January 20, 2014

807.92(a)(2)

Trade Name: MyLabSix Ultrasound System

Common Name: Ultrasound Imaging System

Classification Name(s):	Ultrasonic pulse Doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
	Diagnostic ultrasonic transducer	892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

Predicate Device(s)

K111302, K132231 and K132466	MyLabSeven	Esaote SpA
K083882	MyLabFive	Esaote Europe B.V.

Additional substantial equivalence information is provided in the following substantial equivalence comparison table.

Device Description

The MyLabSix is a mainframe ultrasound system used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, Amplitude Doppler (AD), Tissue Enhancement Imaging (TEI), XView, Multi View (MView), Trapezoidal View (TP View), Tissue Velocity Mapping (TVM), RF-based Quality Intima Media Thickness (QIMT), Color Flow Mapping (CFM) and Pulse Wave Doppler.

The MyLabSix is equipped with a free orientable LCD Color Display where acquired images and advanced images are shown.

A second LCD Display for additional controls and mode-depending keys, includes touch screen technology and is integrated in the control panel.

The MyLabSix can drive phased (PA), convex (CA), linear array (LA) probes, Doppler probes and Volumetric probes.

The MyLabSix is equipped with an internal Hard Disk and with an DVD-RW disk drive that can be used for image storage. Data can also be stored directly to external archiving media (Hard-Disk, PC, server) via a LAN/USB port.

The MyLabSix is manufactured under an ISO 9001:2008 and ISO 13485:2003 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's **MyLabSix** ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

Technological Characteristics

Esaote Europe B.V. believes that the MyLabSix is substantial equivalent to Esaote's MyLabSeven product (K111302, K132231 and K132466) and Esaote's MyLabFive (K083882).

- Clinical uses for which the MyLabSix is designed are equivalent to those cleared for Esaote's MyLabSeven and MyLabFive .
-
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive are designed to meet the IEC60601-1 and the IEC60601-2-37 safety requirements.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive provides an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive provides a similar measurements and analysis package, with equal accuracy and precision.
- The MyLabSix, Esaote's MyLabSeven and Esaote's MyLabFive have a digital storage capabilities, including Network connectivity.
- The MyLabSix image modes are available on other FDA cleared ultrasound systems, for instance Esaote's MyLabSeven and Esaote's MyLabFive.

Summary of Non-Clinical Tests

The MyLabSix has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- NEMA UD-3 – Standard for Real time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 – Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

Conclusion

The MyLabSix is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Esaote Europe B.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

July 11, 2014

Re: K141486
Trade/Device Name: MyLabSix Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 5, 2014
Received: June 9, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLabSix Ultrasound System, as described in your premarket notification:

Transducer Model Number		
AC2541	SC3421	SC3123
SE3123	AL2442	SL3332
SL1543	SL3323	SL3235
SP2730	S2MCW	S5MCW
SHFCW	SB2C41	ST2612
LOT342		

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Handwritten signature of Michael D. O'Hara in cursive script, followed by the word "for" in a smaller font.

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141486

Device Name

MyLabSix Ultrasound System

Indications for Use (Describe)

Esaote's MyLabSix ultrasound system is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small Organs, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative Abdominal, and Other: Urologic. The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)



6420

intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)	
	B	M	FWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	N	N	N	N	N	N	N	N	N	N	N	5, 7
Abdominal	N	N	N	N	N	N	N	N	N	N	N	5, 7
Intraoperative (Abdominal)	N	N	N	N	N	N	N	N	N	N	N	5
Intraoperative Neurological												
Pediatric	N	N	N	N	N	N	N	N	N	N	N	5
Small Organs [1]	N	N	N	N	N	N	N	N	N	N	N	5
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N	N	5
Adult Cephalic	N	N	N	N	N	N	N	N	N	N	N	5
Cardiac [2]	N	N	N	N	N	N	N	N	N	N	N	3
Transesophageal (Cardiac)	N	N	N	N	N	N	N	N	N	N	N	5
Transesophageal (Non Cardiac)												
Transrectal	N	N	N	N	N	N	N	N	N	N	N	5
Transvaginal	N	N	N	N	N	N	N	N	N	N	N	5
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N	N	5
Laparoscopic												
Musculo-skeletal Conventional [3]	N	N	N	N	N	N	N	N	N	N	N	5
Musculo-skeletal Superficial [3]	N	N	N	N	N	N	N	N	N	N	N	5
Other (Urological)	N	N	N	N	N	N	N	N	N	N	N	5

N: New Indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (M+CW)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

- 1 AC2541
- 2 SC3421
- 3 SC3123
- 4 SE3123
- 5 AL2442
- 6 SL3332
- 7 SL1543
- 8 SL3323
- 9 SL3235
- 10 SP2730
- 11 S2MCW
- 12 S5MCW
- 13 SHFCW
- 14 SB2C41
- 15 ST2612
- 16 IOT342

AC2541

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows

Clinical Application	Modes of Operation									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (FVM)	Harmonic Imaging (HE)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	S
Abdominal	P	P	P		P	P	P		P	S
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	S
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	S
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	S
Other (Urological)	P	P	P		P	P	P		P	S

The AC2541 probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CFT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SC3421

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	FWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5
Abdominal	P	P	P		P	P	P		P	5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	5
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transcranial										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	5
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	5
Other (Urological)	P	P	P		P	P	P		P	5

The SC3421 probe is already cleared via K101605

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (MView)

[6] includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SC3123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)	
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	N	N	N		N	N	N		M			S
Abdominal	N	N	N		R	N	N		N			S
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	P	P	P		P	P	P		P			S
Small Organs [1]	P	P	P		P	P	P		P			S
Neonatal Cephalic	P	P	P		P	P	P		P			S
Adult Cephalic												
Cardiac [2]	P	P	P		P	P	P		P			S
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transarterial												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P		P			S
Laparoscopic												
Musculo-skeletal Conventional	P	P	P		P	P	P		P			S
[3]												
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P			S
Other (Urological)												

The SC3123 probe is already cleared via K101605 and to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B-M+PW+CW+CFM+PD

[5] Compound Imaging (Merge)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 13D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SE3123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	5
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	5
Transvaginal	P	P	P		P	P	P		P	5
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)	P	P	P		P	P	P		P	5

The SE3123 probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (M+view)

[6] Includes contrast (Cn(Ti)) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

AL2442

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operations										Other (specify)	
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	P	P	P		P	P	P		P		P	5
Abdominal	P	P	P		P	P	P		P			5
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	P	P	P		P	P	P		P		P	5
Small Organs [1]	P	P	P		P	P	P		P		P	5
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]	P	P	P		P	P	P		P		P	5
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P	P		P		P	5
Laparoscopic												
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		P	5
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		P	5
Other (Urological)												

The AL2442 probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B•M•PW•CW•CFM•PD

[5] Compound Imaging (Mview)

[6] Includes contrast (CnT) in Adult. Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SL3332

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	N	N	N		N	N	M		N	5
Abdominal	N	N	N		N	N	N		N	5
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N		N	5
Small Organs [1]	N	N	N		N	N	N		N	5
Neonatal Cephalic										
Adults Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	5
Trans-sophageal (Cardiac)										
Trans-sophageal (Non Cardiac)										
Transcranial										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N		N	5
Laparoscopic										
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N	5
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N	5
Other (Urological)										

The SL3332 probe is to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (cNTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SL1543

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined (4)	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	S
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	S
Small Organs [1]	P	P	P		P	P	P		P	S
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	S
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	S
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	S
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	S
Other (Urological)										

The SL1543 probe is already cleared via K132231

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound imaging (Mview)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SL3323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (VVM)	Harmonic Imaging (HEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P		P	S
Intraoperative (Abdominal)	P	P	P		P	P	P		P	S
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	S
Small Organs [1]	P	P	P		P	P	P		P	S
Neonatal Cephalic	P	P	P		P	P	P		P	S
Adult Cephalic										
Cardiac [2]	N	N	N		N	N	N		N	S
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	S
Laparoscopic										
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P	S
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P	S
Other (Urological)										

The SL3323 probe is already cleared via K101605 and to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (MTrack)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SL3235

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined (4)	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	N	N	N		N	N	N	N	N	S
Small Organs [1]	N	N	N		N	N	N	N	N	S
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	N	N	N		N	N	N	N	N	S
Laparoscopic										
Musculo-skeletal Conventional	N	N	N		N	N	N	N	N	S
[3]										
Musculo-skeletal Superficial [3]	N	N	N		N	N	N	N	N	S
Other (Urological)										

The SL3235 probe is to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mvivo)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SP2730

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operations										Other (specify)	
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal	N	N	N	N	N	N	N	N	N	N		
Abdominal	N	N	N	N	N	N	N	N	N	N		
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric	N	N	N	N	N	N	N	N	N	N		
Small Organs [1]												
Neonatal Cephalic	N	N	N	N	N	N	N	N	N	N		
Adult Cephalic	N	N	N	N	N	N	N	N	N	N		
Cardiac [2]	N	N	N	N	N	N	N	N	N	N		
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N	N	N	N	N	N	N	N		
Laparoscopic												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial [3]												
Other (Urological)												

The SP2730 probe is to be cleared via this submission

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PI

[5] Compound Imaging (Mview)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

S2MCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Applications	Modes of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

The S2MCW probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PT

[5] Compound imaging (MView)

[6] Includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

S5MCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Modes of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (HE)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Periphereal Vascular										
Laparoscopic										
Musculo-skeletal Conventional [3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

The S5MCW probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (M+view)

[6] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SB2C41

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)	
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (HE)			
Ophthalmic												
Fetal	P	P	P		P	P	P		P			5, 7
Abdominal	P	P	P		P	P	P		P			5, 7
Intraoperative (Abdominal)												
Intraoperative Neurological												
Pediatric												
Small Organs [1]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]												
Transesophageal (Cardiac)												
Transesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional												
[3]												
Musculo-skeletal Superficial [3]												
Other (Urological)												

The SB2C41 probe is already cleared via K132231

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mvix)

[6] Includes contrast (CnT) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

SHFCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations							Harmonic Imaging (TEI)	Color Velocity Mapping (TVM)	Other (specify)
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]			
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

The SHFCW probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (Mview)

[6] Includes contrast (ChTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

ST2612

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (HEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organs [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	P	P	S
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
[3]										
Musculo-skeletal Superficial [3]										
Other (Urological)										

The ST2612 probe is already cleared via N132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (MVIW)

[6] Includes contrast (ChTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)

IOT342

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations										Other (specify)	
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (AD)	Combined [4]	Color Velocity Mapping (TVM)	Harmonic Imaging (TEI)			
Ophthalmic												
Fetal												
Abdominal	P	P	P		P	P			P			S
Intraoperative (Abdominal)	P	P	P		P	P			P			S
Intraoperative Neurological												
Pediatric	P	P	P		P	P			P			S
Small Organs [1]	P	P	P		P	P			P			S
Neonatal Cephalic												
Adult Cephalic												
Cardiac [2]												
Transoesophageal (Cardiac)												
Transoesophageal (Non Cardiac)												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P		P	P			P			S
Laparoscopic												
Musculo-skeletal Conventional [3]	P	P	P		P	P			P			S
Musculo-skeletal Superficial [3]	P	P	P		P	P			P			S
Other (Urological)												

The IOT342 probe is already cleared via K132466

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] Compound Imaging (MView) includes contrast (CnTI) in Adult Cardiac for left ventricle opacification and visualization of the left ventricular endocardial border.

[7] 3D/4D

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of Center for Devices and Radiological Health (CDRH)